



DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 5 2005

Food and Drug Administration
Rockville MD 20857

Roger E. Salisbury, MD
Professor of Surgery, Chief of Plastic Surgery
New York Medical College
Director of Burn of Center Westchester Medical Center
Macy Pavillion
Valhalla, New York 10595

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Re: Docket No. 2005P-0072/CP1

Dear Dr. Salisbury:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated February 15, 2005, submitted on behalf of seven petitioners. Your petition requests that the Food and Drug Administration (FDA) take the following actions:

- conduct a risk assessment of Stevens Johnson Syndrome (SJS) and toxic epidermal necrolysis (TEN) associated with the use of ibuprofen products;
- conduct an investigation into manufacturers' withholding of critical safety information regarding the risks of SJS and TEN associated with ibuprofen products; and
- require manufacturers of ibuprofen to amplify their prescription and over-the-counter labeling to adequately warn prescribers, health care professionals and consumers of the risks of SJS and TEN.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Nonetheless, I would like to call your attention to the fact that FDA has directed manufacturers to make labeling changes to ibuprofen and other non-steroidal anti-inflammatory drugs that include additional warnings regarding the risks of SJS and TEN. This result is consistent with part of the relief requested in your petition. A comprehensive posting of FDA's actions regarding these products can be found at www.fda.gov/cder/drug/infopage/COX2/default.htm#NSAIDletters.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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